TRANSMATTA	Docket No. 18688				
Re Application Of	: Kathryn E. Lawl	or et al.			
Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation N
10/525,363	February 23, 2005	Unassigned	23389	Unassigned	5197
		Address to: Commissioner for Paten P.O. Box 1459	ts		
		Alexandria, VA 22313-14 37 CFR 1.97(b)	50		
of a nation three mont application;	nal application other this of the date of ent the before the mailing o	tement submitted herewith is than a continued prosecution ry of the national stage as set of a first Office Action on the matter st for continued examination un	application un t forth in 37 CF erits, or before	der 37 CFR 1.5 R 1.491 in an ir the mailing of a	3(d); within iternational
		37 CFR 1.97(c)			
CFR 1.97(I Final Actio	b), provided that the on under 37 CFR 1.	tement submitted herewith is Information Disclosure State 113, a Notice of Allowance the application, and is accomp	ment is filed b under 37 CFF	efore the mailing R 1.311, or an	date of a
☐ the s	statement specified in	n 37 CFR 1.97(e);			
	(OR			
☐ the f	fee set forth in 37 CF	R 1.17(p).			

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT Docket No. NOV 1 4 2005 (Under 37 CFR 1.97(b) or 1.97(c)) 18688 Kathryn E. Lawlor et al. Filing Date Application No. Examiner Customer No. Group Art Unit | Confirmation No. 10/525,363 February 23, 2005 Unassigned 23389 Unassigned 5197 Title: A METHOD OF TREATMENT AND PROPHYLAXIS Payment of Fee (Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p)) A check in the amount of is attached. 19-1013/SSMP The Director is hereby authorized to charge and credit Deposit Account No. as described below. Charge the amount of Credit any overpayment. Charge any additional fee required. Payment by credit card. Form PTO-2038 is attached. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. Certificate of Transmission by Facsimile* Certificate of Mailing by First Class Mail I hereby certify that this correspondence is being deposited I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fa with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to *Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on November 10, 2005 (Date) (Data) Signature Signature of Person M. Edward W. Grolz Typed or Printed Name of Person Signing Certificate Typed or Printed Name of Person Mailing Certificate *This certificate may only be used if paying by deposit account. Dated: November 10, 2005 Edward W. Grolz Registration No. 33,705 SCULLY, SCOTT, MURPHY & PRESSER

(516) 742-4343 CC: EWG:ah

400 Garden City Plaza - Suite 300 Garden City, New York 11530

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Kathryn E. Lawlor et al.

Examiner:

Unassigned

Serial No.:

10/525,363

Art Unit

Unassigned

Filed:

February 23, 2005

Docket:

18688

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For: A METHOD OF TREATMENT

AND PROPHYLAXIS

Dated:

November 10, 2005

Confirmation No:

: 5197

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. United States Patent No. 5,420,109 dated May 30, 1995, issued to Suto et al.;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 10, 2005.

Dated: November 10, 2005

Edward W. Grolz

- United States Patent No. 5,639,455, dated June 17, 1997, issued to Shimomura et al.;
- 3. United States Patent Application Publication No. 2002/0141994 dated October 3, 2002, issued to Devalaraja et al.;
- International Patent Publication No. 95/21864, dated August 17, 1995;
- International Patent Publication No. 95/21867, dated August 17, 1995;
- International Patent Publication No. 02/07676, dated January 31, 2002;
- 7. Bernard, L.A. et al., "Pimecrolimus 1% Cream (Elidel[®]) For Atopic Dermatitis," *Skin Therapy Letter*. 7(4): 1-3, (2002);
- Campbell, Ian et al., "The Colony-Stimulating Factors and Collagen-Induced Arthritis: Exacerbation of Disease by M-CSF and G-CSF and Requirement for Endogenous M-CSF," J. of Luekocyte Bio. 68: 144-150, (2000);
- Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatoid Arthritis," Clin. Orthopaedics and Related Research. 379S: S288-S299, (2000);
- Hermans, Mirjam et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF in Mice with a Severe Congenital Neutropenia/Acute Mmyeloid Leukemiaderived Mutation in the G-CSF Receptor Gene," J. Exp. Med. 189(4): 683-691 (1999);
- 11. Caporali, Roberto et al., "Cyclophosphamide Plus Granulocyte Colony Stimulating Factor (G-CSF) is More Effective than G-CSF Alone in Mobilizing Hemopoietic Progenitor Cells in Severe, Refractory Rheumatoid Arthritis," Haematologica. 86(1): 106-107 (2001);
- 12. Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," *J. of Immunology*. 162: 5957-5964, (1999);
- Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human II-1 Receptor Antagonist cDNA Using an Adenoviral Vector," *Human Gene Therapy*. 6: 307-316, (1995); and
- Saggio, I. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," Gene Therapy. 4: 839-845, (1997).

10525363 - GAU: 1647

Reference numbers 1-3, 7-10 and 12-14 were cited in an International Search

Report, dated November 20, 2003, a copy of the search report was filed on February 23, 2005,

therefore a copy is not provided. Applicants are submitting copies of reference numbers 7-10

and 12-14.

In accordance with the waiver of 37 C.F.R. § 1.98 (a)(2)(i) in effect as of June

30, 2003, applicants are not required to submit copies of the U.S. Patent references (reference

numbers 1-3).

Reference numbers 4-6 and 11 were cited in a Supplementary Partial European

Search Report dated July 28, 2005. Applicants are submitting a copy of the search report

together with a copy of the references. The relevance of these references has been described in

the Search Report.

Consideration of this Information Disclosure Statement is respectfully requested,

since the art provided may be material to the examination of the present application as defined

under 37 C.F.R. §1.56.

Inasmuch as this Information Disclosure Statement is being submitted in

accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted.

Edward W. Grolz

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EWG:ar/ab

Enclosure: Form PTO 1449

NOV 1 4 2005					Docket Number (Optional) 18688 Applicant(s) Kathryn E. Lawlor et al.				
					Filing Date February 23,	2005	Group Art Unit Unassigned		
12	-	E)	U.	.S. PATENT	DOCUMENTS			- Songaru	
EXAMINER	REF.	DOCUMENT NUMBER	DATE	Τ	NAME	CLASS	SUBCLASS	FILING DATE	
CMW/		5,420,109	5/30/1995	Suto et	al	H .		IF APPROPRIATE	
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			U.S. PATEN	NT APPLIC	ATION PUBLICATIONS				
EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME		CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
/CMW/		2002/0141994	10/3/2002	Devala	raja et al.	***************************************			
			FOR	EIGN PATE	ENT DOCUMENTS				
	REF	DOCUMENT NUMBER	DATE		COUNTRY		SUBCLASS	Translation YES NO	
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/CMW/		Bernard, L.A. et al.,	"Pimecrolimus 1%	o Cream (E	lidel) For Atopic Derma	titis," Skin The	erapy Letter. 7(4)	: 1-3, (2002);	
/CMW/		Campbell, Ian et al. and G-CSF and Req	"The Colony-Stimu uirement for Endo	ulating Fac genous M-4	tors and Collagen-Induc CSF,"J. of Luekocyte Bi	ed Arthritis: È b. 68: 144-150,	xacerbation of E (2000);	lisease by M-CSF	
EXAMINE	R	/Cherie M. Woodwa	ırd/		DATE CONSIDERED	01/02/20	008		
EXAMINE not conside	R: Ini	tial if citation considered, whet nclude copy of this form with a	her or not citation is text communication to	in conforma o applicant.	nce with MPEP Section 60	9; Draw line thr	ough citation if no	in conformance and	

(also form PTO-1449)

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(Use several sheets if necessary)

Kathryn E. Lawlor et al.

Filling Date
Group Art Unit
Unassigned

*EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
/CMW/	Ghivizzani, Steve C. et al., "Gene Therapy Approaches for Treating Rheumatold Arthritis," Clin. Orthopaedics and Related Research, 3795: \$288-\$299, (2000);					
	Hermans, Mirjam H.A. et al., "Sustained Receptor Activation and Hyperproliferation in Response to Granulocyte Colony-Stimulating Factor (G-CSF) in Mice With a Severe Congenital Neutropenia/Acute Myeloid Leukemia-Derived Mutation in the G-CSF Receptor Gene," J. Exp. Med. 189(4): 683-691 (1999);					
	Caporali, Roberto et al., "Cyclophosphamide Plus Granulocyte Colony Stimulating Factor (G-CSF) is More Effective Than G-CSF Alone in Mobilizing Hemopoletic Progenitor Cells in Severe, Refractory Rheumatoid Arthritis," Haematologica. 86(1): 106-107 (2001);					
	Kawamura, Hiroki et al., "Expansion of Extrathymic T Cells as Well as Granulocytes in the Liver and Other Organs of Granulocyte-Colony Stimulating Factor Transgenic Mice: Why They Lost the Ability of Hybrid Resistance," J. of Immunology, 162: 5957-5964, (1999); Roessler, Blake J. et al., "Inhibition of Interleukin-1-Induced Effects in Synoviocytes Transduced with the Human IL-1 Receptor Antagonist cDNA Using an Adenoviral Vector," Human Gene Therapy. 6: 307-317, (1995); and					
/CMW/	Saggio, L. et al., "Adenovirus-Mediated Gene Transfer of a Human IL-6 Antagonist," Gene Therapy.4: 839-845, (1997).					
EXAMINER	/Cherie M. Woodward/ DATE CONSIDERED 01/02/2008					
*EXAMINER:	Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and					

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not considered. Include copy of this form with next communication to applicant.